Rec'd SEA 8/05/09

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON AT SEATTLE

UNITED STATES OF AMERICA, STATE OF CALIFORNIA, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, DISTRICT OF COLUMBIA, STATE OF FLORIDA, STATE OF GEORGIA, STATE OF HAWAI'I, STATE OF ILLINOIS, STATE OF INDIANA, STATE OF IOWA, STATE OF LOUISIANA, STATE OF MARYLAND, COMMONWEALTH OF MASSACHUSETTS, STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF MONTANA, STATE OF NEVADA, STATE OF NEW HAMPSHIRE, STATE OF NEW JERSEY, STATE OF NEW MEXICO, STATE OF NEW YORK, STATE OF NORTH CAROLINA, STATE OF OKLAHOMA, STATE OF RHODE ISLAND, STATE OF TENNESSEE, STATE OF TEXAS, STATE OF VERMONT, COMMONWEALTH OF VIRGINIA, STATE OF WASHINGTON, ex rel. by SCEF, LLC, LYNNE LEVIN-GUZMAN, and STANLEY JEAN, .

Plaintiffs,

v.

ASTRAZENECA PLC, ASTRAZENECA PHARMACEUTICALS, L.P., VIRTUAL MARKETING STRATEGIES INC., INVENTIV HEALTH, INC., PUBLICIS HEALTHCARE SOLUTIONS, INC., and TRIPLEFIN, LLC,

Defendants.

No. 17-CV-1328 RSL

COMPLAINT AND JURY DEMAND
FILED UNDER SEAL PURSUANT TO
31 U.S.C. § 3730(b)(2)

Date Action Filed: September 1, 2017

FILED UNDER SEAL

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This is a civil qui tam action brought on behalf of the United States of America, the State of California, the State of Colorado, the State of Connecticut, the State of Delaware, the District of Columbia, the State of Florida, the State of Georgia, the State of Hawai'i, the State of Illinois, the State of Indiana, the State of Iowa, the State of Louisiana, the State of Maryland, the Commonwealth of Massachusetts, the State of Michigan, the State of Minnesota, the State of Montana, the State of Nevada, the State of New Hampshire, the State of New Jersey, the State of New Mexico, the State of New York, the State of North Carolina, the State of Oklahoma, the State of Rhode Island, the State of Tennessee, the State of Texas, the State of Vermont, the Commonwealth of Virginia, the State of Washington, ex rel. by SCEF, LLC, Lynne Levin-Guzman, and Stanley Jean, against AstraZeneca, PLC, AstraZeneca Pharmaceuticals, L.P., Virtual Marketing Strategies Inc., InVentiv Health, Inc., Publicis Healthcare Solutions, Inc., and Triplefin, LLC, subject to the qui tam provisions of the Civil False Claims Act, pursuant to 31 U.S.C. §§ 3729-33, as well as the applicable provisions of the respective State False Claims Act laws.

A written disclosure of substantially all material evidence and information the Plaintiffs-Relators possess was served on the United States Government pursuant to 31 U.S.C. § 3730(b)(2) on August 17, 2017. A copy of this complaint will be served on the United States Government pursuant to 31 U.S.C. § 3730(b)(2) and Rule 4(i) of the Federal Rules of Civil Procedure on September 1, 2017. Copies of this complaint and a written disclosure of substantially all material evidence and information the Plaintiffs-Relators possess will be served on the state governments pursuant to 31 U.S.C. § 3732(c) and Rule 4(j) of the Federal Rules of Civil Procedure on September 1, 2017. This complaint is filed in camera, under seal, and may not be served upon the Defendants until further order of this Court.

I. NATURE OF THE ACTION

1. Defendants AstraZeneca, PLC and AstraZeneca Pharmaceuticals, L.P. (collectively "Astra Defendants" or "Astra"), manufacture, market, and sell various drugs

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including Brilinta, Bydureon, and Symbicort (collectively "Covered Drugs"). In an effort to increase their sales of these Covered Drugs, Astra devised two intertwined, unlawful drug marketing schemes, both of which violate the False Claims Act ("FCA"), 31 U.S.C. §§ 3279 et seq., and analogous state laws.

2. First, beginning in approximately 2012 up and through the present, the Astra Defendants paid tens of millions of dollars to Defendants Virtual Marketing Strategies, Inc., (dba VMS BioMarketing), InVentiv Health, and Publicis Healthcare Solutions, Inc. (dba Publicis Touchpoint Solutions, Inc.), (collectively "Clinician Provider Companies") to employ health care professionals—in particular, specialty Nurses and Respiratory Care Specialists—as "educators" (hereinafter "Clinical Educators"). Astra used these Clinical Educators to recommend specific Astra Defendants' drugs—Brilinta, Bydureon, and Symbicort—to both Prescribers (e.g., physicians) and patients under the guise of education and counseling—a variation on a scheme the Office of the Inspector General ("OIG") refers to with repudiation as "white coat marketing."

3. Second, also since at least 2012, the Astra Defendants and Defendants VMS BioMarketing, InVentiv Health, and Publicis Touchpoint Solutions provided remuneration in the form of free, in-kind services from Clinicians to prescribers in order to induce those healthcare providers to recommend or prescribe Astra's Covered Drugs to patients—a more typical unlawful "quid pro quo" kickback scheme. Astra, along with Defendant Triplefin, also provided free reimbursement support services to prescribers to induce them to recommend Astra's Covered Drugs to patients. As a result of these schemes, prescribers have and continue to submit claims to Medicare and Medicaid that were tainted by these staffing services kickbacks, causing these programs to pay tens of millions of dollars in improper reimbursements. These schemes are ongoing.

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4. Defendants' schemes undermine the independent decision making of prescribers, an important element in Government Healthcare Program coverage policy. The healthcare providers prescribing the Astra Defendants' Covered Drugs did not necessarily do so because they believed, based on their review of peer-reviewed medical literature or discussion with their colleagues, that the drugs would help their patients. Rather, the Astra Defendants' Covered Drugs were and are often supplied because Defendants actively and improperly pursued and enticed prescribers with free services and other forms of remuneration.

5. As a result of these schemes, prescribers have submitted and continue to submit claims to Medicare and Medicaid that were tainted by kickbacks, causing these programs to pay tens of millions of dollars in improper reimbursements.

6. Knowingly paying kickbacks to induce physicians to prescribe a drug on-label or off-label (or to influence physician prescriptions) for individuals who seek reimbursement for the drug from a Federal Government health program or causing others to do so, while certifying compliance with the AKS (or while causing another to so certify), or billing the Government as if in compliance with these laws, violates the FCA and similar State False Claims Acts.

7. Based upon personal knowledge, relevant documents, investigations and information and belief, Relator SCEF, LLC, Relator Levin-Guzman, and Relator Jean (collectively "Clinician-Relators"), through their undersigned attorneys, bring this qui tam action on behalf of the United States of America pursuant to the FCA as well as the analogous state false claims laws of the States or Commonwealths of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawai'i, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Vermont,

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Virginia, Washington, and the District of Columbia, (collectively "State Governments "). Plaintiffs-Relators seek to recover treble damages sustained by, and civil penalties and restitution owed to, the United States Government and the State Governments.

II. JURISDICTION AND VENUE

8. This Court has jurisdiction over the claims Relators bring on behalf of the United States under the FCA pursuant to 28 U.S.C. §§ 1331 and 1345. This Court has supplemental jurisdiction over the claims asserted under the laws of the State of California, the State of Colorado, the State of Connecticut, the State of Delaware, the District of Columbia, the State of Florida, the State of Georgia, the State of Hawai'i, the State of Illinois, the State of Indiana, the State of Iowa, the State of Louisiana, the State of Maryland, the Commonwealth of Massachusetts, the State of Michigan, the State of Minnesota, the State of Montana, the State of Nevada, the State of New Hampshire, the State of New Jersey, the State of New Mexico, the State of New York, the State of North Carolina, the State of Oklahoma, the State of Rhode Island, the State of Tennessee, the State of Texas, the State of Vermont, the Commonwealth of Virginia, and the State of Washington, pursuant to 28 U.S.C. § 1367(a) and 31 U.S.C. § 3732(b).

9. The Court may exercise personal jurisdiction over Defendants pursuant to 31 U.S.C. § 3732(a) because at least one Defendant can be found or transacts business in this District, and/or an act proscribed by 31 U.S.C. § 3729 occurred in this District.

10. Venue is appropriate in this District pursuant to 31 U.S.C. § 3732 because Defendants transact business in this District and, in furtherance of their fraudulent kickback schemes, caused to be submitted or conspired to submit false claims in this District. Venue is also appropriate pursuant to 28 U.S.C. § 1391(b) and (c) because a substantial part of the events that give rise to the United States' claims occurred in this District, and Defendants reside in this

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District.

11. A civil action for a violation of the False Claims Act may be brought by private persons on behalf of the United States Government under the qui tam provisions of 31 U.S.C. § 3730(b). Similarly, each State Government Plaintiff has a false claims law that is analogous to the federal FCA and permits a knowledgeable relator to participate in the State's recovery.

12. Relators are the original source of the information and facts upon which the allegations in this Complaint are based. Relators have direct and independent knowledge of the information and facts contained in this Complaint based upon their own investigation and analyses as well as an investigation undertaken on their behalf through their Counsel.

13. To the best of Relators' knowledge, there has been no prior public disclosure of the allegations contained in this Complaint. There are no known published studies, reports, or articles that have previously identified the schemes identified in this Complaint. Relators performed independent research and analyses to confirm, to the best of their ability, the false claims that they identify in this Complaint.

14. Further, Relators' Complaint is not based upon the public disclosure of allegations or transactions in any criminal, civil, or administrative hearing or any congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation or from the news media.

15. To the extent that there has been any public disclosure unknown to Relators, each is an original source under 31 U.S.C. § 3730(e)(4), and the applicable provisions of the respective State False Claims Act laws.

16. Relators have complied with 31 U.S.C. § 3730(b)(2) by voluntarily providing the information to the United States before filing this action and serving a copy of the Complaint

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upon the Government.

III. PARTIES

A. Plaintiffs

17. The United States and the State Governments—specifically, the Department of Health and Human Services ("HHS"), including its components, the Centers for Medicare and Medicaid Services ("CMS"), the Office of Inspector General, and the Medicare and Medicaid Programs—are the real parties in interest under the False Claims Act and analogous state laws.

18. The United States paid the false claims alleged in this Complaint through Medicare, federal health insurance programs administered by the CMS for the elderly and disabled. *See* 42 U.S.C. §§ 1395 et seq.

19. The State Governments have analogous state-specific statues modeled on the Federal FCA which apply to the state portion of Medicaid losses caused by false Medicaid claims to jointly federal-state funded Medicaid programs. The Plaintiff State Governments each fund health insurance programs.

B. Relators

20. Relator SCEF, LLC, is a New Jersey-based entity organized under the laws of the State of Delaware and formed to investigate and act as co-Relator for the matters alleged herein.

21. Relator Lynne Levin-Guzman was employed by InVentiv Health as a Cardiovascular Nurse Educator contracting with AstraZeneca Pharmaceuticals, L.P., from approximately June 2013 until July 31, 2015. Relator Levin-Guzman is a resident of Los Angeles County, California.

22. Relator Stanley Jean was employed by InVentiv Health as a Respiratory Care Specialist contracting with Astra from approximately April 2014 until August 2015 when the

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Clinician Provider Company with whom Astra contracted changed to Publicis Touchpoint Solutions. Relator Jean was employed by Publicis as a Respiratory Care Specialist contracting with AstraZeneca Pharmaceuticals, L.P., from August 2015 until January 31, 2016. Relator Jean is a resident of Westchester County, New York.

C. Defendants

23. Defendant AstraZeneca, PLC ("Astra PLC") is an Anglo-Swedish multinational pharmaceutical and biopharmaceutical company that is headquartered in Cambridge, England, and was formed in 1999 with the merger of Astra AB and Zeneca Group PLC. It is a Fortune 500 company that is publicly-traded and conducts business throughout the United States, including through its operations of a Maryland-based biologics division called MedImmune, that conducts research and development for its biopharmaceuticals, as well as in other countries. Astra PLC reported total revenue of over $26 billion in 2014 and $24 billion in 2015.

24. Defendant AstraZeneca Pharmaceuticals, L.P. ("Astra") is a Delaware corporation. Astra operates as a subsidiary of Astra PLC and its commercial business headquarters are in Wilmington, Delaware. Astra has research and development, manufacturing, and commercial office locations in California, Delaware, Kentucky, Massachusetts, Maryland, North Carolina, Ohio, and Pennsylvania. Astra engages in the discovery, development, manufacture, and delivery of bio-therapeutics (e.g., prescription drugs) for various medical needs including the Covered Drugs. From 2012 to the present, Astra co-promoted the Covered Drugs along with Astra PLC and both are liable for any unlawful promotion up and through that time.

25. Defendant Virtual Marketing Strategies Inc., dba VMS BioMarketing ("VMS") is a healthcare marketing company headquartered in Indianapolis, Indiana. Beginning by no later than 2014, VMS provided Clinical Educators to Astra to sell the Covered Drug Bydureon.

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26. Defendant InVentiv Health, Inc. ("InVentiv") is a biopharmaceutical professional services company headquartered in Burlington, Massachusetts. InVentiv is privately owned by InVentiv Group Holdings, Inc., a New Jersey organization sponsored by affiliates of Thomas H. Lee Partners, L.P., Liberty Lane Partners, and members of the InVentiv management team. In May of 2017, InVentiv announced that it was merging with INC Research to form a global biopharmaceutical solutions company, that will be headquartered in North Carolina. INC Research shareholders will own 53% of the combined company. InVentiv shareholders will own 47%. Beginning by at least 2012 through approximately July 2015, InVentiv provided Astra with Clinical Educators to sell the Covered Drug Symbicort.

27. Defendant Publicis Healthcare Solutions, Inc., dba Publicis Touchpoint Solutions, Inc., ("Publicis") designs and implements healthcare sales, service, and clinical teams, and is headquartered in Pennsylvania. Publicis operates as a subsidiary of Publicis Healthcare Communications Group, Inc, a healthcare communications network. Beginning no later than July 2015, Publicis began providing Clinical Educators to Astra to sell the Covered Drugs Brilinta and Symbicort. In addition, Publicis employed Pharmaceutical Field Customer Service Associates for certain drugs including Symbicort, this appears to be a hybrid job position combining the roles of a drug representative with that of reimbursement personnel.

28. Defendant Triplefin, LLC ("Triplefin") develops patient access and adherence brand solutions for pharmaceutical manufacturing companies, including by providing reimbursement support programs to pharmaceutical companies. It is based in Cincinnati, Ohio. As of 2013, Triplefin operates as a subsidiary of Smith Medical Partners LLC. Beginning no later than 2015, Triplefin provided reimbursement support to Astra for Covered Drug Brilinta.

29. Defendants Astra PLC, Astra, VMS, InVentiv, Publicis, and Triplefin are

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collectively referred to as "Defendants" unless noted otherwise herein.

30. At all times material to this action, the Defendants were participating providers in the Medicare and Medicaid Programs and were transacting business in this District.

IV. STATUTORY BACKGROUND

A. The False Claims Act

31. The FCA establishes treble damages liability to the United States for any individual or entity that:

> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; [or]
>
> (C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G)[.] 31 U.S.C. § 3729(a)(1)(A)-(C).

Within the meaning of the FCA, "knowing" is defined to include reckless disregard and deliberate ignorance. 31 U.S.C. § 3729(b)(1)(ii)-(iii).

32. In addition to treble damages, the FCA also provides for assessment of a civil penalty for each violation or each false claim ranging from $5,500 to $11,000. *See, e.g.*, Civil Monetary Penalties Inflation Adjustment, 64 Fed. Reg. 47,099, 47,104 (Aug. 30, 1999).

B. The Anti-Kickback Statute

33. The Anti-Kickback Statute ("AKS"), 42 U.S.C. §§ 1320a-7b et seq., states as follows in relevant part:

> (b) Illegal remunerations
>
> (1) whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

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> (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.
>
> (2) whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—
>
> (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b(b)(1)-(2).

34. For purposes of the AKS, "remuneration" includes the transfer of anything of value, in cash or in-kind, directly or indirectly, covertly or overtly. Importantly, the statute has been interpreted to cover any arrangement where one purpose of the remuneration is to obtain money for referral of services or to induce further referrals.

35. The AKS is designed to, among other things, ensure that patient care will not be improperly influenced by inappropriate compensation from the pharmaceutical industry.

36. In order to ensure compliance, every federally-funded health care program requires every provider or supplier to ensure compliance with the provisions of the AKS and other Federal laws governing the provision of health care services in the United States.

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37. The AKS was amended in March 2010 as part of the Patient Protection and Affordable Care Act ("PPACA"), which clarified that all claims resulting from a violation of the AKS are also a violation of the FCA. 42 U.S.C. § 1320a-7b(g). The PPACA also amended the Social Security Act's "intent requirement" to make clear that violations of its anti-kickback provisions, like violations of the FCA, may occur even if an individual does "not have actual knowledge" or "specific intent to commit a violation." PPACA, Pub. L. No. 111-148, § 6402(h), 124 Stat. 119, 759 (2010).

38. Knowingly providing kickbacks to healthcare providers to induce them to prescribe a drug (or to influence provider prescriptions) for individuals who seek reimbursement for the drug from a Federal Government healthcare program or causing others to do so, while certifying compliance with the AKS (or while causing another to so certify), or billing the Government as if in compliance with these laws, violates the FCA.

39. The Balanced Budget Act of 1997 amended the AKS to include administrative civil penalties of $50,000 for each violation, as well as an assessment of not more than three times the amount of remuneration offered, paid, solicited, or received, without regard to whether a portion of that amount was offered, paid, solicited, or received for a lawful purpose. *See* 42 U.S.C. § 1320a-7a(a).

40. The AKS contains statutory exceptions and certain regulatory "safe harbors" that exclude certain types of conduct from the reach of the statute. *See* 42 U.S.C. § 1320a-7b(b)(3). None of the statutory exceptions or regulatory safe harbors protect Defendants from liability for the conduct alleged herein. Compliance with the AKS is a condition of payment under Federal health care programs.

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V. AFFECTED HEALTH PROGRAMS

41. For the drugs at issue in this case, generally, when a physician prescribes a drug, a patient is provided with a prescription that is then filled at a pharmacy. The pharmacy then submits the claim for payment to the relevant Federal health care program(s) for reimbursement.

42. In certain circumstances, a Federal program may also have pharmacy facilities that directly dispense prescription drugs. In such cases, the Federal health care program purchases the drug directly rather than reimbursing the pharmacy.

A. Medicare

43. Medicare is a Federal program that provides Federally subsidized health insurance primarily for persons who are 65 or older or disabled. *See* 42 U.S.C. §§ 1395 et seq. ("Medicare Program"). Part D of the Medicare Program was enacted as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003), to provide prescription drug benefits for Medicare beneficiaries. Medicare Part D became effective January 1, 2006. All persons enrolled in Medicare Part A and/or Medicare Part B are eligible to enroll in a prescription drug plan under Part D. The United States Department of Health and Human Services ("HHS"), through its component agency, the Centers for Medicare and Medicaid Services ("CMS"), contracts with private companies (or "Part D sponsor(s)") to administer prescription drug plans. Such companies are regulated and subsidized by CMS pursuant to one-year, annually renewable contracts. Part D sponsors enter into contracts and subcontracts with many pharmacies to provide drugs to the Medicare Part D beneficiaries enrolled in their plans.

44. Generally, after a physician writes a prescription for a patient who is a Medicare beneficiary, that patient can take the prescription to a pharmacy to be filled. When the pharmacy

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dispenses drugs to the Medicare beneficiary, the pharmacy submits a claim electronically to the beneficiary's Part D sponsor (sometimes through the sponsor's pharmacy benefit manager ("PBM")). The pharmacy receives reimbursement from the sponsor (or PBM) for the portion of the drug cost not paid by the beneficiary. The Part D sponsor is then required to submit to CMS an electronic notification of the drug dispensing event, called the Prescription Drug Event ("PDE"), which contains data regarding the prescription claim, including the service provider of the drug, the prescriber of the drug, the quantity dispensed, the amount it has paid to the pharmacy, and whether the drug is covered under the Medicare Part D benefit.

45. Payments to a Part D Plan sponsor are conditioned on the provision of information to CMS that is necessary for CMS to administer the Part D program and make payments to the Part D Plan sponsor for qualified drug coverage. 42 C.F.R. § 423.322 (2015). CMS's instructions for the submission of Part D prescription PDE claims data state that "information . . . necessary to carry out this subpart" includes the data elements of a PDE. *Id.* PDE records are an integral part of the process that enables CMS to administer the Part D benefit. Each PDE that is submitted to CMS is a summary record that documents the final adjudication of a dispensing event based upon claims received from pharmacies and serves as the request for payment for each individual prescription submitted to Medicare under the Part D program.

46. CMS gives each Part D sponsor advance monthly payments consisting of the Part D sponsor plan's direct subsidy per enrollee (which is based on a standardized bid made by the Part D sponsor), estimated reinsurance subsidies for catastrophic coverage, and estimated low income subsidies. 42 C.F.R. § 423.315 (2005), 42 C.F.R. § 423.329 (2015). At the end of the payment year, CMS reconciles the advance payments paid to each Part D sponsor with the actual

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costs the sponsor has incurred. In this reconciliation process, CMS uses the PDE claims data it has received from the Part D sponsor during the prior payment year to calculate the costs the Part D sponsor has actually incurred for prescriptions filled by Medicare beneficiaries under Part D. If CMS underpaid the sponsor for low-income subsidies or reinsurance costs, it made up the difference. If CMS overpaid the sponsor for low-income subsidies or reinsurance costs, it recouped the overpayment from the sponsor. After CMS reconciles a plan's low-income subsidy and reinsurance costs, it then determines risk-sharing amounts owed by the plan to CMS or by CMS to the plan related to the plan's direct subsidy bid. Risk-sharing amounts involve calculations based on whether and to what degree a plan's allowable costs exceeded or fell below a target amount for the plan by certain threshold percentages. 42 C.F.R. § 423.336 (2005).

47. CMS's payments to the Part D sponsor come from the Medicare Prescription Drug Account, an account within the Federal Supplementary Medical Insurance Trust Fund. 42 C.F.R. § 423.315(a) (2005).

48. In order to receive Part D funds from CMS, Part D Plan sponsors, as well as their authorized agents, employees, and contractors (including pharmacies), are required to comply with all applicable Federal laws, regulations, and CMS instructions.

49. By statute, all contracts between a Part D Plan sponsor and HHS must include a provision whereby the Plan sponsor agrees to comply with the applicable requirements and standards of the Part D program as well as the terms and conditions of payment governing the Part D program. 42 U.S.C. § 1395w-112(b)(1).

50. Medicare Part D Plan sponsors must also certify in their contracts with CMS that they agree to comply with all Federal laws and regulations designed to prevent fraud, waste, and abuse, including the FCA and AKS. 42 C.F.R. § 423.505(h)(1) (2017).

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51. In accordance with these express statutory and regulatory requirements, all contracts entered into between CMS and Part D Plan sponsors from 2006 through the present include a provision in which the sponsor "agrees to comply with [] Federal laws and regulations designed to prevent fraud, waste, and abuse, including, but not limited to applicable provisions of Federal criminal law, the False Claims Act (31 U.S.C. [§§] 3729 et seq.), and the anti-kickback statute (section 1128B(b) of the Act)." *Id.*

52. CMS regulations further require that all contracts between Part D Plan sponsors and first tier, downstream, and related entities (such as pharmacies and PBMs) contain language obligating those entities to comply with all applicable Federal laws, regulations, and CMS instructions. 42 C.F.R. § 423.505(i)(4)(iv) (2017).

53. A Part D Plan sponsor also is required by Federal regulation to certify to the accuracy, completeness and truthfulness of the PDE claims data submitted to CMS. Specifically, the relevant regulatory provision, entitled "Certification of data that determine payment," provides in relevant part:

> (1) General rule. As a condition for receiving a monthly payment under subpart G of this part (or for fallback entities, payment under subpart Q of this part), the Part D plan sponsor agrees that its chief executive officer (CEO), chief financial officer (CFO), or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must request payment under the contract on a document that certifies (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of all data related to payment. The data may include specified enrollment information, claims data, bid submission data, and other data that CMS specifies.
>
> (2) Certification of enrollment and payment information. The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that each enrollee for whom the organization is requesting payment is validly enrolled in a program offered by the organization and the information CMS relies on in determining payment is accurate, complete, and truthful and acknowledge that this information will be used for the purposes of obtaining Federal reimbursement.

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> (3) Certification of claims data. The CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the claims data it submits under § 423.329(b)(3) (or for fallback entities, under § 423.871(f)) are accurate, complete, and truthful and acknowledge that the claims data will be used for the purpose of obtaining Federal reimbursement.

42 C.F.R. § 423.505(k)(1)-(3) (2017).

54. Compliance with the regulatory requirement that the PDE data submitted to CMS is "true, accurate, and complete" is a condition of payment under the Medicare Part D program to the extent that it involves a violation of the AKS.

55. In accordance with this regulatory requirement, since the Part D program began, Medicare has required each Part D Plan sponsor to sign annually an Attestation of Data Relating to CMS Payment to a Medicare Part D Sponsor ("Attestation"). This Attestation states:

> Pursuant to the contract(s) between the Centers for Medicare & Medicaid Services (CMS) and the Medicare Part D Organization(s) listed above, hereafter referred to as the Part D Organization, governing the operation of the contract numbers listed above, the Part D Organization hereby makes the following attestations concerning CMS payments to the Part D Organization:
>
> The Part D Organization attests that based on its best knowledge, information, and belief, the final Prescription Drug Event (PDE) data that have been submitted to and accepted by CMS as of [date] with respect to the Part D plans offered under the above-stated contract(s) for the dates of service of January 1, [prior year] to December 31, [prior year], are accurate, complete, and truthful and reflect all retroactive adjustments of which the Part D organization has been informed by May 30, [current year]. In addition, the Part D Organization attests that based on best knowledge, information, and belief, the payments that have been made by the Part D organization for the claims summarized by the aforementioned PDE data were made in accordance with the coordination of benefits guidance in Chapter 14 of the Medicare Prescription Drug Benefit Manual and other applicable CMS guidance. The Part D Organization attests that based on its best knowledge, information, and belief as of the date(s) of last successful DIR [Direct and Indirect Remuneration Data] [prior year] data submission(s) via the Health Plan Management System (HPMS) as listed above, the final direct and indirect remuneration data submitted to CMS for the Part D plans offered under the above-stated contract(s) for the [prior] coverage year are accurate, complete, and truthful and fully conform to the requirements in the Medicare Part D program

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> regulations and the Final Medicare Part D DIR Reporting Requirements for [the prior year]. The Part D Organization also certifies that based on its best knowledge, information, and belief as of the date indicated below, all other required information provided to CMS to support the determination of allowable reinsurance and risk corridor costs for the Part D plans offered under the above-stated contract(s) is accurate, complete, and truthful. With regards to the information described in the above paragraphs, the Part D Organization attests that it has required all entities, contractors, or subcontractors, which have generated or submitted said information (PDE and DIR data) on the Part D Organization's behalf, to certify that this information is accurate, complete, and truthful based on its best knowledge, information, and belief. In addition, the Part D Organization attests that it will maintain records and documentation supporting said information. The Part D Organization acknowledges that the information described in the above paragraphs will be used for the purposes of obtaining federal reimbursement and that misrepresentations or omissions in information provided to CMS may result in Federal civil action and/or criminal prosecution.[1]

56. All approved Part D Plan sponsors who received payment under Medicare Part D in benefit years 2006 through the present date submitted these required Attestations in the same or similar format.

57. Medicare regulations further provide:

> If the claims data are generated by a related entity, contractor, or subcontractor of a Part D plan sponsor, the entity, contractor, or subcontractor must similarly certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the data and acknowledge that the claims data will be used for the purposes of obtaining Federal reimbursement.

42 C.F.R. § 423.505(k)(3) (2017).

58. Medicare also enters into agreements with physicians to establish the physician's eligibility to participate in the Medicare program. For the physician to be eligible for participation in the Medicare program, physicians must certify that they agree to comply with the AKS, among other Federal health care laws. Specifically, on the Medicare enrollment form,

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[1] *See 2008 Regional Prescription Drug Event Data Technical Assistance - Resource Guide* at 385, CMS (2008), https://www.csscoperations.com/internet/Cssc.nsf/files/2008-regional-pde-resource-guide.pdf/$FIle/2008-regional-pde-resource-guide.pdf.

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CMS Form 855I, the "Certification Statement" that the medical provider signs states: "You MUST sign and date the certification statement below in order to be enrolled in the Medicare program. In doing so, you are attesting to meeting and maintaining the Medicare requirements stated below."[2] Those requirements include:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to me . . . . The Medicare laws, regulations and program instructions are available through the fee-for-service contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier's compliance with all applicable conditions of participation in Medicare.
>
> . . .
>
> I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity.

Id.

B. Medicaid

59. Medicaid is a joint Federal-State program created in 1965 that provides health care benefits for certain groups, primarily the poor and disabled. Each state administers a State Medicaid program. The Federal Medicaid statute requires each participating State to implement a plan containing certain specified minimum criteria for coverage and payment of claims. 42 U.S.C. §§ 1396, 1396a(a)(13), (30)(A). While drug coverage is an optional benefit, the Medicaid programs of all states provide reimbursement for prescription drugs.

60. The Federal portion of each state's Medicaid payments, known as the Federal Medical Assistance Percentage ("FMAP"), is based on the state's per capita income compared to

[2] *Medicare Enrollment Application - Physicians and Non-Physician Practitioners (CMS-855I)* at 25, CMS (July 2011), https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms855i.pdf.

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the national average. 42 U.S.C. § 1396d(b). Among the states, the FMAP is at least 50 percent and is as high as 83 percent. Federal funding under Medicaid is provided only when there is a corresponding state expenditure for a covered Medicaid service to a Medicaid recipient. The Federal government pays to the state the statutorily established share of the "total amount expended . . . as medical assistance under the State plan." 42 U.S.C. § 1396b(a)(l).

61. The vast majority of states award contracts to private companies to evaluate and process claims for payment on behalf of Medicaid recipients. Typically, after processing the claims, these private companies then generate funding requests to the state Medicaid programs. Before the beginning of each calendar quarter, each state submits to CMS an estimate of its Medicaid federal funding needs for the quarter. CMS reviews and adjusts the quarterly estimate as necessary, and determines the amount of federal funding each state will be permitted to draw down as it incurs expenditures during the quarter. The state then draws down federal funding as actual provider claims, including claims from pharmacies seeking payment for drugs, are presented for payment. After the end of each quarter, the state then submits to CMS a final expenditure report, which provides the basis for adjustment to the quarterly federal funding amount (to reconcile the estimated expenditures to actual expenditures). 42 C.F.R. § 430.30 (2016).

62. Claims arising from illegal kickbacks are not authorized to be paid under state regulatory regimes. In fact, providers who participate in the Medicaid program must sign enrollment agreements with their states that certify compliance with the State and Federal Medicaid requirements, including the AKS. Although there are variations among the states, the agreement typically requires the prospective Medicaid provider to agree that he or she will comply with all State and Federal laws and Medicaid regulations in billing the state Medicaid

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program for services or supplies furnished.

63. Furthermore, in many states, Medicaid providers, including both physicians and pharmacies, must affirmatively certify compliance with applicable Federal and State laws and regulations.

64. For example, in New York, physicians and pharmacies must periodically sign a "Certification Statement for Provider Billing Medicaid," in which the provider certifies that claims submitted "to the State's Medicaid fiscal agent, for services or supplies furnished, [...] will be subject to the following certification. . . . I (or the entity) have furnished or caused to be furnished the care, services, and supplies itemized and done so in accordance with applicable Federal and State laws and regulations[.]"[3]

C. TRICARE

65. TRICARE (formerly known as CHAMPUS), is part of the United States military's health care system, designed to maintain the health of active duty service personnel, provide health care during military operations, and offer health care to non-active duty beneficiaries, including dependents of active duty personnel, and military retirees and their dependents. The military health system, which is administered by the Department of Defense ("DOD"), is composed of the direct care system, consisting of military hospitals and military clinics, and the benefit program, known as TRICARE. TRICARE is a triple-option benefit program designed to give beneficiaries a choice between health maintenance organizations, preferred provider organizations, and fee-for-service benefits.

[3] *Certification Statement for Provider Billing Medicaid* at 1, (Dec. 2010), https://www.emedny.org/info/providerenrollment/ProviderMaintForms/490501_ETIN_CERT_Certification_Statement_Cert_Instructions_for_Existing_ETINs.pdf.

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66. TRICARE prescription drug benefits are provided through three different programs: military treatment facility outpatient pharmacies, TRICARE network retail pharmacies and TRICARE's mail order service. TRICARE contracts with a PBM to administer its retail and mail order pharmacy programs. In addition, TRICARE beneficiaries can also pay out-of-pocket to fill prescriptions at non-network retail pharmacies, and submit a claim for reimbursement directly with TRICARE's PBM. The claims process is different for each of these pharmaceutical programs.

67. When a TRICARE beneficiary brings a prescription to a TRICARE network retail pharmacy, for example, the pharmacy submits an electronic claim to the PBM for that prescription event. The PBM sends an electronic response to the pharmacy that confirms the beneficiary's TRICARE coverage, and, if the prescription claim is granted, informs the pharmacy of the calculated pharmacy reimbursement amount and the co-pay (if applicable) to be collected from the beneficiary. The pharmacy then collects the co-pay amount (if any) from the beneficiary and dispenses the medication. After a 10-day hold to ensure the prescription was picked up and not returned to the shelf by the pharmacy, the PBM sends a TRICARE Encounter Data ("TED") record electronically to TRICARE. The TED record includes information regarding the prescription event, including the reimbursement amount to be paid to the dispensing pharmacy. TRICARE then authorizes the PBM to make payment to the pharmacy for the amount remaining (after co-pay) on the claim. The PBM sends the payment to the pharmacy. After the payment is made by the PBM's bank, the PBM's bank requests reimbursement from the Federal Reserve Bank. The Federal Reserve Bank then transfers funds to the PBM's bank account.

68. If the prescription is filled at a non-network retail pharmacy, the beneficiary must

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pay the full price of the prescription to the pharmacist and file a claim for reimbursement on DD Form 2642, TRICARE DoD/CHAMPUS Medical Claim - Patient's Request for Medical Payment ("Form 2642").[4] The Form 2642 is mailed to the PBM. As in the case of reimbursements under the retail pharmacy program, a TED record is created and sent to TRICARE. TRICARE then authorizes payment to the TRICARE beneficiary. Upon receiving that authorization, the PBM issues a check to the beneficiary, which is drawn on the PBM's bank account. TRICARE then reimburses the PBM in the same manner as it does under the retail pharmacy program, such that funds are transferred from the Federal Reserve Bank to the PBM's bank account.

69. TRICARE beneficiaries can also fill prescriptions through TRICARE's mail order pharmacy program as well. TRICARE beneficiaries submit prescriptions by mail, fax, or electronically to TRICARE's PBM, along with any co-pay (if applicable). TRICARE's PBM delivers the prescription to the beneficiary via free standard shipping. The medications dispensed through the mail order pharmacy program are filled from the PBM's existing inventory of pharmaceuticals. The PBM then requests replenishment pharmaceuticals from DOD's national prime vendor contracted by Defense Logistics Agency. DOD procures the pharmaceuticals through its national prime vendor and replenishes the PBM's inventory of pharmaceuticals after accumulated dispensing reach full package size amounts. The PBM then submits a TED record to TRICARE to obtain administrative fees in connection with that prescription event. The Defense Logistics Agency bills TRICARE directly for drug replenishment costs.

70. Pursuant to 38 U.S.C. § 8126, pharmaceutical manufacturers are required to enter

[4] *TRICARE DoD/CHAMPUS Medical Claim - Patient's Request for Medical Payment*, (Apr. 2007), http://www.esd.whs.mil/Portals/54/Documents/DD/forms/dd/dd2642.pdf.

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into national contracts with the DOD pursuant to which the manufacturer makes available for procurement certain covered drugs at the Federal Ceiling Price (a price that is calculated as at least 24% less than the manufacturer's average price based on all sales to commercial customers through a wholesaler or distributor). Pursuant to DOD's contract with its national prime vendor, the national prime vendor submits an invoice to the DOD for payment of pharmaceuticals supplied to the PBM in connection with the mail order pharmacy program, charging the DOD the price set by the contract awarded by the DOD to the drug manufacturer.

71. Since March 2003, TRICARE has contracted with a pharmacy benefits manager, Express Scripts, Inc. ("ESI"), to administer TRICARE's mail order pharmacy programs. ESI has also administered TRICARE's retail pharmacy program since June 2004.

72. Similarly, TRICARE's military treatment facilities purchase medications through procurement contracts with third party pharmaceutical prime vendors. When a TRICARE beneficiary submits an outpatient prescription to a military treatment facility's outpatient pharmacy, the pharmacy purchases the medication from the prime vendor pursuant to an existing procurement contract, and the drug is then dispensed to the patient.

73. While some physicians enroll in the TRICARE program as network or participating providers, any physician that is licensed, accredited and meets other standards of the medical community is authorized to provide services to TRICARE beneficiaries. Physicians who are enrolled in the TRICARE network must expressly certify their compliance with TRICARE's regulations. Yet all providers that provide services to TRICARE beneficiaries, whether network providers or non-participating providers, are required to comply with TRICARE's program requirements, including its anti-abuse provisions. 32 C.F.R. § 199.9(a)(4) (2013). TRICARE regulations provide that claims submitted in violation of TRICARE's anti-

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abuse provisions can be denied. *Id.* § 199.9(b). Kickback arrangements are included within the definition of abusive situations that constitute program fraud. *Id.* §§ 199.2(b) (2016), 199.9(c)(12) (2013).

D. Veterans Administration Health Care

74. The Department of Veteran Affairs ("VA") maintains a system of medical facilities from which all pharmaceutical supplies, including prescription drugs, are procured directly by the VA. A VA beneficiary can take a prescription to a VA medical facility, at which point the VA dispenses the medication to the VA beneficiary from its existing inventory. The VA also supports a mail service prescription program as part of its outpatient drug benefit. VA beneficiaries can submit prescriptions to that mail service program, and the VA then dispenses pharmaceuticals purchased by the VA directly to VA beneficiaries. The VA medical system serves approximately four million veterans.

75. The VA purchases the pharmaceuticals that it dispenses at its medical facilities and through its mail service prescription program through its Federal Supply Schedule program. Pursuant to 38 U.S.C. § 8126, pharmaceutical manufacturers are required to enter into national contracts with the VA pursuant to which the manufacturer makes available for procurement certain covered drugs at the Federal Ceiling Price (a price that is calculated as 26% less than the manufacturer's average price based on all sales to commercial customers through a wholesaler or distributor). A VA facility that requires a supply of a particular medication (including a mail order facility) submits a purchase order to the VA's pharmaceutical prime vendor ("PPV") for distribution of pharmaceuticals. The PPV fills the order for the facility, and then submits an invoice to the VA for payment, charging the VA the price set by the contract awarded by the VA to the drug manufacturer. The VA makes payment to the PPV. The PPV then seeks a chargeback

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from the drug manufacturer for any difference between the contract price paid by the VA and the PPV' s acquisition price.

76. Pursuant to the Affordable Care Act, among other things, all claims to Government reimbursed programs resulting from a violation of the AKS are also a violation of the FCA.

77. Moreover, the statutes and regulations set forth above concerning Medicare, Medicaid, TRICARE, and the Veterans Administration Health Care, when viewed together, state that healthcare providers must comply with the AKS in order for claims they cause to be submitted to these programs to be reimbursed. The claims submitted here for Astra's Drugs violated the AKS in that these claims stemmed from prescriptions written by providers in exchange for bribes knowing that claims for reimbursement would be submitted to the above programs as a result. As such, and as more fully discussed below, the prescribing healthcare providers expressly and impliedly falsely certified compliance with the conditions of payment for, at least, Medicare, Medicaid, TRICARE, and the Veterans Administration Health Care.

78. In addition to falsely certifying compliance with the AKS, the healthcare providers referred to herein also falsely certified compliance with contractual provisions that were conditions for payment.

VI. THE COVERED DRUGS

79. The three Covered Drugs at issue in Defendants' fraudulent schemes were Brilinta, Bydureon, and Symbicort.

A. Brilinta

80. Brilinta is a prescription medicine used to treat people who have had a heart attack or severe chest pains due to insufficient oxygen supply. Brilinta is used with aspirin to

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lower the chance of blood clots by preventing platelets (blood cells that help with normal blood clotting) from sticking together and forming a clot that can block an artery. Brilinta is a tablet that is taken by mouth.

81. In 2014, there were 249,000 Medicare Part D Claims for Brilinta at a retail cost of $75.1 million according to ProPublica. State Governments had between 109 and 23,849 Medicare Part D claims ranging in cost from $34,400 to $7,310,000. In 2015, the number of Medicare Part D claims for Brilinta rose to 377,000 at a retail cost of $129 million.

B. Bydureon

82. Bydureon is a prescription medication that may improve blood sugar in adults with type 2 diabetes. Bydureon is injected under the skin of a patient's stomach, thigh or upper arm one time per week.

83. In 2014, there were 180,000 Medicare Part D Claims for Bydureon at a retail cost of $98.6 million according to ProPublica. State Governments had between 33 and 18,212 Medicare Part D claims ranging in cost from $20,300 to $9,580,000. In 2015, there were 130,000 Medicare Part D claims for Bydureon at a retail cost of $83 million.

C. Symbicort

84. Symbicort is a medication used for the maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease ("COPD"), including chronic bronchitis and emphysema, and for asthma patients. Symbicort is an inhalation aerosol and is administered through an inhaler.

85. In 2014, there were 3.15 million Medicare Part D Claims for Symbicort at a retail cost of $942 million according to ProPublica. State Governments had between 2,754 and 271,022 Medicare Part D claims ranging in cost from $842,000 to $80,600,000. In 2015, the

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number of Medicare Part D claims for Symbicort rose to 3.69 million at a retail cost of $1.2 billion.

VII. DEFENDANTS' FRAUDULENT SCHEMES

86. Astra contracted with the Clinician Provider Companies (and other unnamed co-conspirators) for a force of Clinical Educators to work with Astra's sales team to promote Astra's Covered Drugs. Clinical Educators are health care professionals who possess training, knowledge and experience in disease management, pre-disease care, and disease prevention. A Clinical Educator certification is "practice based" and requires health care professionals to gain professional experience working in the field.

87. Certified Clinical Educators are recognized as specialty Clinicians with particular training, education, and experience in disease education and care. Not surprisingly, Clinical Educators are in particular demand for healthcare providers who care for disease patients. Many Clinical Educators are employed by hospitals, and primary care and specialty practices to work with disease patients. As Clinicians with significant training, education and experience, Clinical Educators can command significant compensation in the healthcare workforce.

A. Scheme One: Clinical Educators Used for Unlawful "White Coat Marketing"

88. The Astra Defendants paid the Clinician Provider Companies (and others) to unlawfully promote their Covered Drugs using Clinical Educators.

89. Astra realized that potential prescribers were frequently refusing to meet with their drug salespeople about Astra's disease drugs. Indeed, many facilities have strict policies relating to access to the facilities by pharmaceutical drug and medical device company representatives. These policies include only allowing representatives to discuss medications available through a facility's formulary, thereby making it extremely difficult to introduce newer

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drugs to potential prescribers in those facilities.

90. The Astra Defendants sought to overcome these barriers by using an unlawful marketing scheme through its relationships with the Clinician Provider Companies.

91. Beginning no later than 2012, Astra entered into relationships with the Clinician Provider Companies (and others) whereby the Clinician Provider Companies would use Clinical Educators to gain access to facilities and providers (or others who had any impact on a prescriber's purchasing decisions such as nurses and practice administrators) in order to market Astra's Covered Drugs.

92. Astra believed that, as expert Clinicians, the Clinician Provider Companies' Clinical Educators were more likely than drug salespeople to obtain access to prescribers because Clinical Educators would be able to talk on a "peer to peer" level with providers and their staff regarding the diseases and their treatments.

93. Relators confirm that Clinical Educators were viewed by healthcare providers as more credentialed and, thus, more credible than Astra's drug salespeople. Clinical Educators were told to play up their title and background.

94. To further increase their chances to access target facilities and prescribers, Astra and Clinician Provider Companies recruited health care professionals from facilities to which they sought access. Witnesses across the country who were hired to "educate" on the disease states addressed by the Covered Drugs observed that Clinicians, including Clinician-Relators themselves, were often assigned to facilities where they had previously worked and/or had pre-existing relationships with facility or medical personnel.

95. Astra paid the Clinician Provider Companies tens of millions of dollars for the Clinical Educators workforce.

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1. Clinical Educators Are Trained Like Drug Reps

96. Each of the Clinician Provider Companies' Clinical Educators underwent a rigorous Astra training program which included disease state as well as compliance training, in addition to training on particular sales techniques—similar to the program each Astra drug sales representative undergoes. The training involved studying and passing timed tests relating to the disease state and drug chemistry, as well as role playing scenarios regarding, for example, effective public speaking and how to overcome objections from provider-gatekeepers to get in the door of a facility.

97. Once trained, Astra started to deploy the Clinician Provider Companies' Clinical Educators across the country to call on healthcare providers who could prescribe the Astra Covered Drugs.

98. According to Clinician-Relators as well as a number of Clinical Educator witnesses, Astra participated in or conducted their training along with the Clinician Provider Companies. Clinician-Relators as well as a number of Clinical Educator witnesses received sales training such as training to overcome objections, field questions, close a call, ask for patients at the end of a call, and "elevator" speeches (short sales pitches if a Clinical Educator caught a doctor in an elevator). According to Relator Levin-Guzman, she received "basically training as a sales rep [drug rep]."

99. Clinical Educators for Symbicort and Brilinta used the sales computer programs "Sales Force" and "Veeva" to report back to Astra after they had been in the field.

2. Gaining Access to Prescribers through Astra's Clinical Educators

a. Gaining access through prior relationships

100. Once trained, Astra selectively deployed Clinical Educators to target providers

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that were identified as likely to generate the greatest sales of Astra's drugs.

101. At the day-to-day level, this involved Astra providing a call or target list to their third-party-employed Clinical Educators.

102. Astra also deployed Clinical Educators specifically to facilities with whom the Clinical Educators had a prior relationship.

103. For example, Relator Levin-Guzman, a Brilinta Clinical Educator, not only helped Astra gain access to facilities and health care providers with whom she previously worked, she was able to get Brilinta added to the formulary of one of her prior places of employment, Methodist Hospital of Southern California in Arcadia, California.

104. Relator Jean, a Symbicort Clinical Educator, said he was introduced by the Astra sales team to either accounts with low sales or to the best accounts as a "value-added." He said a lot of the contacts he targeted were directed by the sales team. In addition, Relator Jean believes he was hired because of his prior experience as an employee in respiratory services at Montefiore Hospital where he had access to the Director of Respiratory Services. Relator Jean specifically stated the goal was to gain access to that facility; "that['s] their strategy." Relator Jean later learned that Montefiore Hospital was a "no call" facility (i.e., a facility does not allow any type of sales professional on site), and while he had been able to gain access as a Symbicort educator, he was there "against their policy."

b. Gaining access under the guise of education

105. Astra needed a clever and nuanced approach to disguise this marketing strategy. After all, Astra knew that Clinical Educators could not openly appear to act in the role of drug salespeople for several reasons. One, Astra feared that providers would limit Clinical Educator access in the same manner that drug sales representative access was being limited. Two, if Astra

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openly admitted that Clinical Educators were promoting its drugs, Astra would be forced to lawfully restrict the Clinical Educators' messaging to only FDA-approved marketing materials or risk a charge of "off label" promotion. And, three, the OIG refers to this type of marketing as "white coat" (i.e., utilizing Clinicians to promote drugs) as particularly suspect.

106. As a result, Astra created contrived disease awareness programs that obscured the true role for the Clinical Educators—these programs were intended to make Clinical Educators appear to be functioning distinct and independent from the role of drug salespersons.

107. In doing so, Astra designated the Clinical Educators as "educators" who, instead of selling drugs, were now marketing and promoting the free disease awareness educational services to healthcare providers. But Relators report that they would go months without using their nursing specific skills or not use their nursing skills at all, and that, despite being told they were being sent out to "educate," their roles became almost completely sales based.

108. The Clinician Provider Company InVentiv explains for example, that InVentiv offers "[s]elling [s]olutions" to "create extraordinary growth" by "deploy[ing] highly-skilled teams, nurse-educators and medical science liaisons who speak their language." InVentiv advertises, "[p]artner with us to reduce your fixed cost investments while increasing your sales and marketing effectiveness."

109. The Clinician Provider Company VMS posts job listings for "Clinical Educator" jobs that make clear that the Clinical Educator will "[w]ork and communicate cohesively with territory sales force members to meet area needs, identify collaborative opportunities, and execute territory plan." One of the required skills for the job is the "[a]bility to demonstrate a strong sense of urgency in program requests and outstanding customer service to multiple audiences (e.g., pharmaceutical sales . . .)."

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110. The Clinician Provider Company Publicis explains its "Respiratory Educator" job as follows. "Working with pre-approved curriculum the Respiratory Educator will focus on educating healthcare providers. . . . The Respiratory Educator will partner externally as well as internally within a matrixed organization." Applicants are also told that they need to have the "[a]bility to work well within matrixed environment supporting a sales team."

111. Despite using a "form-over-substance" labeling of Clinical Educators to the outside world, the Clinician-Relators as well as witnesses known to the Relators all make clear that the Clinical Educators were drug salespeople by every measure except title. While they were to portray themselves as "educators" to providers, a Clinical Educator witness saw documents from Astra referring to the witness as a "US Field Sales Representative[]" and as a "Sales Professional[]."

112. Relator Jean explained how facilities complained when his "education" sessions turned out to be Symbicort commercials; in other words, he was able to gain access with his credentials as a healthcare professional and under the guise of "education." According to Relator Jean, his role became almost completely sales-based: "I could put [on] my résumé that I've done sales and marketing." An InVentiv manager openly said to Relator Jean, "you guys shouldn't be called educators[.]"

113. Further, Relators and witnesses report that the compensation of the Clinicians was not tied to any education metrics.

3. Astra's "White Coat" Clinical Educators Increased Sales of Covered Drugs

114. The white coat marketing part of the strategy was hugely successful as Astra gained the much coveted "access" to prescribers and patients by using the Clinician Provider Companies' Clinical Educators.

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115. After gaining this access under the auspices of an educational service, the Clinician Provider Companies' Clinical Educators (i.e., "white coat" Clinicians recognized as experts in disease treatments) were now also in an ideal position to exclusively recommend Astra Covered Drugs to prescribers and, more troubling, directly to patients.

116. Witnesses confirm that Astra trained and directed the Clinician Provider Companies' Clinical Educators to directly promote Astra's drugs to prescribers and patients once Clinical Educators gained access to, and were in a position to recommend Astra Covered Drugs to healthcare providers.

117. Witnesses, including Clinician-Relators, confirm that their services increased sales of the Covered Drugs. *See infra* § VII.B.3.

118. Since Astra was paying the Clinician Provider Companies to engage in this conduct, this scheme violates the AKS which makes it unlawful to pay remuneration in exchange for a recommendation of an item paid for by the Government.

119. In this case, Defendants are paying Clinical Educators—medical professionals—to promote Astra's products under the guise of providing prescribers and patients with "education." The act of paying a non-employee third party white coat Clinician to recommend a drug to providers is not protected under any safe harbor exception and thus this conduct violates the AKS.

4. Astra's Seeding Programs

120. Finally, Astra also violates the AKS by and through the utilization of its AZ&Me Prescription Savings Program ("PSP"), a program purportedly designed to help individuals afford their medicine and prescription drug costs.

121. Astra's PSP acts as a "seeding program"—a scheme that the OIG has found

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violates the AKS because such programs act as an inducement to patients to "self-refer" for Astra's Covered Drugs.

122. Although Astra purports to set appropriate eligibility criteria and guidelines, these guidelines are manipulated and ignored in order to initially provide Astra's Covered Drugs for free as an inducement to self-refer—only, upon information and belief, to change the criteria or guidelines in order to maintain or renew the particular Covered Drug under a patient's reimbursable benefits.

123. This scheme includes mandating that a patient apply for certain Government-reimbursed drug coverage (e.g., Medicaid, LIS, Medicare, etc.) so as to cause the patient—who was initially induced because of the "free" or reduced cost drug—to then have that drug's cost reimbursed by government payers.

B. Scheme Two: Providing Free Clinical Educator Services to Physicians as a Quid Pro Quo for Referrals

124. In addition to the white coat marketing scheme, Astra, in a separate but related more traditional kickback scheme, also sought to incentivize disease care healthcare providers to choose Astra Covered Drugs over competitors' drugs.

125. Here, Astra identified the unique and particular needs and challenges that disease care healthcare providers faced in managing their own practices and patients. Once these providers' needs and challenges were identified, Astra, through Clinician Provider Companies began selling these providers "solutions" to those needs and challenges unsolicited and prior to any prescription or additional prescriptions for the Covered Drugs being written.

126. For example, managing disease care for diabetes and COPD patients can be complex—typically requiring multiple medications, and often requiring extra office time, disease training time and additional provider resources to manage patients with these diseases.

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Notwithstanding industry research that demonstrates diabetes and COPD patients require substantial additional time to manage, most providers allocate only between 10 to 15 minutes to see routine patients. Astra also learned that only the largest and most profitable clinics and providers could afford to employ and pay for their own clinical educators, such as Certified Diabetes Educators, to manage their patients. Smaller and less profitable providers were very unlikely to incur the cost of a clinical educator, which cost healthcare practices $50,000 to $100,000 in annual salary, or an average hourly wage of $40.00 per hour.

1. Astra's Clinical Educator Programs

127. Specifically, in response to challenges like these, Astra began a nation-wide program offering and then providing prescribers the time, service and expertise of Clinical Educators (Nurse Educators or other Specialists) employed by a Clinician Provider Company both to help manage that prescribers' disease patients and to provide disease training to the prescribers' staff. The Clinical Educator services ranged from: (i) assisting with practice efficiency; (ii) training on disease care; (iii) eliminating the administrative expense of teaching patients self-injections; and (iv) being "on call" to answer a patients' care questions.

128. The in-kind remuneration offered by Astra most frequently was patient management support services, consisting of group or one-on-one sessions between a Clinical Educator and the prescriber's patient(s) as part of Astra's drugs' programs.

129. For example, Astra's diabetes Clinical Educator program for Bydureon was called "SteadySTART." The SteadySTART website touted an "opportunity to meet face-to-face with a Clinical Educator" as well as "Patient Follow-up Calls." Clinical Educator-Witnesses' estimated there were between 80 and 90 Clinical Educators in the SteadySTART program nationwide, and the program began in or around 2013. More recently, Astra has replaced this program with the

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"12-Week Turnaround Program." This program provides for conversations with your "Clinical Diabetes Educator" to learn how to prepare and take your weekly Bydureon dose, and offered 4 personalized phone calls with your educator to answer questions, provide support, and "help you stay on track with your weekly injections," the program also purportedly offers "personalized support" on "living healthy." In some areas, "in-person" meetings are available. VMS, which also provided Clinical Educators for Bydureon, touts their Clinical Educators on their website by saying "Brands partner with us to provide solutions that make complex therapies easier to understand and simpler to use."

130. Astra's COPD Clinical Educator program for Symbicort is called "AZ Cares," this program included roughly 150 Clinical Educators nationwide. It is unclear exactly when the Symbicort Clinical Educator program began, but Relator SCEF, LLC, has spoken with Clinical Educators who were employed since at least 2014.

131. Astra's Clinical Educators for Brilinta were referred to as "Transition Care Specialists" and were specifically instructed to get prescribers to refer patients during their post-heart attack "transition" so they would begin to use Brilinta.

2. Clinical Educator Services Were Offered to Providers in *Quid Pro Quo* Fashion: Clinical Educator Patient Management in Exchange for Prescriptions

132. Providers were encouraged to enroll all Astra's diabetes, COPD, and heart patients into these "patient support" programs so that the Clinical Educators could begin to directly manage these patients and free the provider from the time and expense of doing so. Astra knew that the program would reduce administrative costs for providers, and, consequently, providers would likely "push" patients to join the program, thereby driving increased sales of Astra drugs.

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133. Once trained and deployed, these Clinical Educators began to offer and provide free education services to any healthcare provider who would prescribe Astra's products. According to Clinician-Relators as well as a number of Clinical Educator-Witnesses, they would offer their services to providers while performing ride alongs with the drug representatives, or when they called on providers on their own using a company-provided call list. Importantly, these calls were in the context of sales calls as the Clinical Educator was working directly with the sales team.

134. According to Relator Jean, the goal was "to become an arm of the office." He held office hours at several pulmonary practices on a regular basis and would be assigned to educate patients on COPD, many of whom did not yet have a prescription for Symbicort.

135. Through the services they provided, the Clinician Provider Companies' Clinical Educators were successful in saving prescribers' time, money, and resources by, for example, (a) allowing providers to refrain from hiring other staff, and (b) allowing providers and their medical staff to spend less time with their patients (quicker/shorter appointments) so they could see additional patients, which resulted in earning additional compensation. In addition, in many instances, the services provided by the Clinical Educators resulted in providers receiving higher reimbursement rates associated with certain disease care metrics.

136. To induce providers to write Astra drug prescriptions, Astra provided remuneration to physicians in the form of the Clinical Educator services described above that were provided through VMS, InVentiv, and Publicis. Of course, in typical *quid pro quo* fashion, in order to be given these services those providers would have to "support" (i.e., write prescriptions for) Astra's disease drugs.

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3. Clinical Educator Access Leads to Increased Prescriptions for Covered Drugs

137. Not surprisingly, Astra saw increased sales of the Covered Drugs after the launch of its Clinical Educator patient education and management program.

138. According to Clinician-Relators as well as a number of Clinical Educator witnesses, these strategies were extremely effective at increasing sales of Astra's covered drugs and this is borne out by the preliminary data available to Relators.

139. For example, Relator Levin-Guzman helped train patient care nurses to have streamlined and targeted (time efficient) discussions with their patients so that patients would get the medication (Brilinta) before they left the hospital and avoid the risk of a secondary heart attack. Brilinta patients were typically in need of oral anti-platelet therapy after stent placement in their coronary vessels. Without this treatment, these cardiac patients could build up platelets that manifest into scar tissue that might result in a fatal heart attack. Of course, there were competitor drugs to Brilinta that did effectively the same thing that were cheaper and generic. Providers however, were informed of the services Relator Levin-Guzman could provide as part of the "education" and sales process and prior to a new Brilinta prescription being written. Relator Levin-Guzman was directed by Astra and/or InVentiv to target Dr. Henry Yee at Garfield Medical Center in California who was already prescribing Brilinta to his patients. Starting in July 2013, Relator Levin-Guzman began calling on Dr. Yee's critical care nurses at Garfield Medical Center that serviced or worked with Dr. Yee, and who could influence Dr. Yee's prescription decisions. In 2012, Dr. Yee wrote 82 prescriptions for Brilinta to Medicare patients. In 2013, Dr. Yee wrote 339 Brilinta prescriptions to Medicare patients, 332 prescriptions in 2014, and 271 prescriptions in 2015. Between the year prior to Relator Levin-Guzman working with Dr. Yee's nurses and the year after she began doing so, Dr. Yee increased

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the number of prescriptions for Brilinta to Medicare patients threefold.

140. Witnesses also reported that Bydureon Clinical Educators would meet with a provider's patient to provide one-on-one injection training, as well as separate diet and exercise trainings for diabetes patients. The injection training took on average about one hour per patient. Having the Bydureon Clinical Educators provide the one-on-one injection training and the follow-up diet and exercise trainings in the place of the prescribers or the prescribers' staff who—would otherwise be responsible for these functions—(a) allowed the prescribers to hire fewer staff for these types of functions, and (b) allowed the prescribers and their staff to see additional patients during the time they otherwise would have spent with a Bydureon patient. Prescribers were informed of the services the Bydureon Clinical Educators could provide as part of the "education" and sales process and prior to a new Bydureon prescription being written. Witnesses reported an increase in Bydureon sales after Clinical Educator services were provided to internal medicine physicians and others.

141. Relator Jean held regular office hours at a few pulmonary practices. Relator Jean would see patients of providers to teach them how to use Symbicort and the inhaler device as well as disease state training for COPD and severe asthma. Providers were informed of the services Relator Jean could provide as part of the "education" and sales process prior to a new Symbicort prescription being written. Relator Jean provided these services—services the prescriber or the prescriber's staff would otherwise be responsible for performing, which (a) allowed the prescribers to hire fewer staff for these types of functions, and (b) freed up the prescriber and the prescriber's staff, allowing them to see additional patients or perform other work while Relator Jean spent time with their patients explaining Symbicort and their patient's medical condition. Based upon the feedback and performance bonuses Relator Jean received, he

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believes there was an increase in Symbicort sales after he began providing these services to the pulmonary practices.

142. This scheme was repeated in states across the United States for all three Covered Drugs.

143. The services provided by the Clinical Educators enabled a prescribing physician to reduce the time or cost required to treat a patient if he or she gets that patient on Astra drugs. The services of the Clinical Educator freed prescribers to see other patients and, thereby, increase their profitability. Under Astra's program, a prescriber could eliminate the time and expense of managing a patient each time s/he prescribed Astra drugs and accepted the services of a Clinical Educator. Further, the more often a healthcare provider prescribed Astra drugs, (as opposed to a competitor drug that did not offer clinical educator services), the more time and cost a provider would save.

144. Astra's provision of educational and other services to prescribers in exchange for recommending its drugs, also violates the AKS.

C. Scheme Three: Free Reimbursement Support Services for Referrals

145. Astra also induced prescribers to recommend its drugs by offering and providing what is referred to as "reimbursement support" services ("RSS") through Astra's Access 360 program for Symbicort[5] or by contracting to provide those services through Defendant Triplefin's Rx365 program for Brilinta.

146. It is a prescriber's responsibility to complete the numerous steps between the

[5] Publicis also employed Pharmaceutical Field Customer Service Associates for certain drugs including Symbicort that appear to be hybrid job positions combining the role of a drug representative with that of reimbursement personnel.

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writing of a prescription and the patient's receipt of the drug. But completing these tasks requires the attention of the prescriber and his or her staff, and each task bears discrete economic costs to the prescriber.

147. According to a study published in 2009 in Health Affairs, primary care prescribers spent a mean of 1.1 hours per week on authorization-related work, primary care nursing staffs spent 13.1 hours, and primary care clerical staff spent 5.6 hours. The same study estimated that the overall cost to the healthcare system of all practice interactions with health plans, including authorizations, was between $23 billion and $31 billion annually.

148. Alternatively, if a prescriber does not wish to pay its own staff members to carry out these tasks, prescribers have the option of outsourcing many of the tasks that lead up to the filling of a prescription, including the work required to obtain pre-authorizations, to third-party commercial vendors that will perform these services for a fee. Medical practices typically pay approximately $75 per initial insurance verification, $40 for insurance re-verification, $75 for prior authorizations, and other à la carte fees. Whether outsourced or performed in-house, the tasks that must be completed before prescriptions are filled result in significant administrative costs to prescribers.

149. Astra and Triplefin offered RSS personnel to work with providers' office staff to help identify drug coverage and out-of-pocket costs for Astra medications. Astra's drug representatives and customer service representatives marketed the RSS to increase the likelihood that prescribers would prescribe Astra drugs. Put simply, in exchange for prescribing Astra drugs, Astra would assume the providers' administrative responsibilities and costs associated with starting a patient on Astra drugs. The more a provider prescribed Astra drugs as a percentage of its overall prescription volume, the greater the savings and profits to the practice,

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because time and money previously spent on handling RSS for Astra drugs would now fall on Astra.

150. Astra and Triplefin openly promote these specific services that they offer to prescribers. The RSS were the "carrot" (remuneration) dangled to induce providers to prescribe Astra drugs to their patients.

1. Astra's "Pitching" of RSS to Providers

151. Astra advertises on its website that it offers the following services to healthcare providers who prescribed the Covered Drugs:

- Pharmacy/Specialty Pharmacy Options: "Access 360 can help determine a patient's pharmacy options including Specialty Pharmacy Providers (SPP). We support the referral process through in-network pharmacy identification (i.e. SPPs contracted with a patient's insurance plan) and submission of prescriptions to a specific pharmacy."
- Referral Follow-Up: "Access 360 can follow up on referral packages submitted to a Retail Pharmacy, SPP, Pharmacy Benefit Manager (PBM), or Payer to confirm receipt, next steps, and medicine shipment date."
- Benefits Investigation: "Access 360 can develop an in-depth report to identify a patient's insurance coverage, authorization requirements, pharmacy options, and patient out-of-pocket costs for both medical and pharmacy benefits."
- Prior Authorization: "Access 360 can identify payer-specific forms, the submission process, and the contacts necessary when a Prior Authorization is required. We can also follow up on the status of the Prior Authorization submission until a decision is reached."
- Appeals: "Access 360 can review denied authorizations/claims and identify payer-specific instructions and forms for submitting an appeal. We provide general appeal letter templates and can connect you to a Medical Information Team for supporting appeal documentation. Access 360 can also follow up with a payer on a submitted appeal until an outcome is obtained."
- General Coding Support: "Access 360 has agents with reimbursement expertise to provide coding, claim, and reimbursement information."

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- Patient Access Programs/Copay Savings Programs: "Access 360 connects patients and their providers to programs available to assist qualified patients with their out-of-pocket medicine costs."

- Patient Assistance Programs/AZ&Me Prescription Savings Program: "Access 360 connects patients and their providers to the AZ&Me program, which helps qualifying people without insurance, those with Medicare Part D, and those who receive their medications through participating health care facilities."

152. Further, Triplefin advertises on its website that it "offers patients and providers multiple points of access to their prescription benefit information through an integrated platform. "It can be built into your brand's website or delivered on a standalone website for patients or providers and serves as a gateway to patient support throughout critical points of therapy." Triplefin also "provides patients and providers a web-based solution for processing a prior authorization, improving efficiency and first-fill completion rates for your brand." Finally, Triplefin offers "a call center component to support the patient or provider for benefit verification and prior authorization assistance" for "additional high touch support."

153. Since no later than 2012, Astra drug salespeople's pitch to healthcare providers in this regard has essentially been as follows:

> Dear Doctor: If you prescribe our drug (i.e., "recommend" the patient to use our drug), we will give you the services and resources of a full reimbursement support team to manage the process associated with prescribing the drug. This service will save you the cost and expenses normally associated with managing a patient's prescription and make your practice more profitable.

154. This value proposition was a powerful tool in the hands of Astra's drug salespeople and was used to influence prescribers to recommend Astra's Covered Drugs. Astra's drug salespeople could offer a prescriber an "on call" reimbursement support team to manage the patient's Astra drug prescriptions. Reimbursement support services became very much a part of the Astra drug salespeople's collective sales pitch to healthcare providers.

155. That is, rather than promoting and marketing its drugs based on patient outcomes

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and efficacy, Astra introduced an additional incentive to entice prescribers to recommend its drugs to patients.

2. Reimbursement Support and Coverage Determination Services are a Tangible Benefit to Providers

156. Astra knew that this service would present a tangible value to the prescribers. RSS are a great value to prescribers because these services reduce, and in some instances eliminate, the administrative costs associated with prescribing drugs for healthcare providers.

157. These services increase profitability for physicians, particularly for "office-based" prescribers because they derive most of their revenue from 15, 30, and 45-minute units of service provided to patients during office visits. The technical term for an office visit is "evaluation-and-management services" or "E/M" for short. In 2012, the most commonly billed Medicare physician service was the $70 "doctor office visit" for a 15-minute consultation, closely followed by the $100 "doctor office visit" for a 30-minute consultation. E/M services cost Medicare "nearly $11 billion in 2012." Medicaid and private insurers also pay billions each year.

158. When an office-based provider receives payment for an E/M service, part of the payment is intended to compensate the provider for medical care given and administrative tasks associated with that patient's care. For example, if a provider receives $50 for an E/M service, a portion of that $50 is intended to compensate the provider for the administrative tasks inherent in managing that patient's care. These tasks include:

1. determining the patient's prescription drug insurance benefit verifications ("Verifications");
2. determining if the drug is on the formulary lists and any applicable tiers;
3. seeking a coverage determination for the drug from the patient's carrier;
4. determining the in-network pharmacy where the patient can have the drug filled;

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5. determining the patient's co-pays, deductibles, and eligibility for "co-pay" cards or coupons;

6. communicating information to the patient;

7. responding to patient complaints;

8. handling prescription refill requests;

9. obtaining "prior authorizations" where necessary; and

10. managing the resulting paper trail.

159. Various studies have estimated that (a) the mean annual projected cost per full-time equivalent physician for prior authorizations alone at between $2,161 and $3,430; and (b) providers spend an annual average of nearly $83,000 of overhead for staff time and other costs associated with coverage issues.

160. Despite these enormous administrative costs and expenses, office-based providers are not permitted to directly charge patients a fee for any of these services pursuant to the payer-physician contract which pays for these services indirectly through the E/M unit charge.

161. Since a provider's E/M reimbursement for each office visit is fixed per unit, providers are continuously seeking ways to combat and reduce overhead costs and expenses in order to earn more profit from each E/M unit billed. One way to do so is to reduce the administrative costs associated with prescribing drugs. If a provider can reduce this cost, each E/M unit will be more profitable.

162. These economics have a direct impact on a prescribers' behavior. Prescribers are less likely to prescribe a drug that imposes an undue burden on support staff because this decreases profitability by requiring more staff and/or reducing the number of patients that can be seen in a day. Conversely, a prescriber is much more likely to prescribe a drug if it can be done with little or no administrative burden. Thus, the prescriber's relative cost and burden in

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prescribing one company's drug when compared to another company's drug can directly influence which drug a prescriber will recommend to a patient.

163. Here, Astra and Triplefin, gave providers an *a la carte* single point of contact to manage the Astra prescription process—which greatly reduced and/or eliminated the providers' overhead and expenses that would otherwise have been associated with any Astra prescription.

164. When a provider accepted Astra's offer of reimbursement support services, the prescriber received the benefits of those services without actually having to pay for them. Providing these services for free to prescribers resulted in greater profit from each prescriber's evaluation and management coding unit charge.

165. Astra's Access 360 program and Triplefin's Rx365 program resulted in a great value to prescribers because they eliminated the time and expense of determining and verifying patients' insurance benefits, determining whether a prescribed drug was on formulary and determining co-pays and deductibles or obtaining prior authorization.

166. Witnesses (experienced reimbursement support personnel) reported that the research for each of these steps would take between fifteen to thirty minutes per patient and then the verification or prior authorization process itself could take anywhere from at least thirty minutes to several hours per patient, depending on the amount of follow-up required. Astra's Access 360 program and Triplefin's Rx365 program also saved healthcare providers' staff time with phone calls to patients because Astra and Triplefin managed each step in the process and communicated with patients directly.

167. Providers also no longer needed to manage a patient's call for refills or additional authorizations because Astra and Triplefin managed those functions for them.

168. Finally, Astra's Access 360 program also provided healthcare providers with free

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"appeals" services for patients—this allowed providers to eliminate the staff time and expense of appealing a patient's denial of benefits as well as the cumbersome prior authorization process.

169. While the reimbursement support services were free to prescribers, they certainly were not free for Astra to manage and run. For example, Astra and Triplefin reimbursement support personnel are paid approximately $15-20 per hour, money that a provider would otherwise need to pay staff if it prescribed a Covered Drug or some other similar drug that did not provide reimbursement support services. Further, over the last ten years, Astra—alone, and sometimes through third parties like Triplefin—invested in technology and specialized personnel in order to develop a concierge of RSS that are marketed to providers along with Astra drugs in order to increase the likelihood that providers choose to recommend Astra drugs. While these services cost millions of dollars to provide, Astra readily incurred this expense, knowing that these services would act as a powerful inducement to providers to recommend Astra drugs over a competitor's drugs.

170. By giving a provider reimbursement support services, Astra gave a tangible "in kind" benefit that greatly reduced and in some instances eliminated a provider's administrative costs related to prescribing Astra Covered Drugs and, thus, induced prescribers to choose Astra Covered Drugs over a competitor's drugs. Such "in kind" remuneration given to induce a recommendation for an Astra drug is an unlawful kickback under the AKS.

VIII. DAMAGES

171. As Defendants profited from the illegal schemes described in this Complaint, Medicare and Medicaid and other government health care programs were made to bear the costs. From 2006 to the present, Defendants' actions knowingly have caused prescribers, Part D sponsors, fiscal intermediaries and others to submit millions of dollars in claims to Medicare and

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Medicaid for Astra's Covered drugs provided to beneficiaries as a result of Defendants' illegal marketing and *quid pro quo* arrangements. Those false claims have caused Medicare and Medicaid and other government health care programs to disburse tens of millions of dollars in reimbursements that should not have been paid.

IX. SUMMARY

172. As is detailed above, Defendants are liable to the Federal and State governments for damages based on the payment of all claims submitted to Federal health care programs for prescriptions written for the Covered Drugs beginning from the time they began paying remuneration up and through the present because the claims were the result of recommendations induced, in whole or in part, by remuneration.

173. Compliance with the AKS is a precondition of payment by virtue of Federal and State statutes, regulations, provider agreements, and contracts.

174. The certifications and attestations signed by physicians, pharmacies, PBMs, and Part D sponsors certified compliance with the AKS. Kickbacks that were paid to and received by Clinician Educators, physicians and other health care professionals, to recommend Astra's Covered Drugs as alleged herein rendered those certifications and attestations false. Those false statements were material to the false claims submitted for the Covered Drugs.

175. Claims for Astra's Covered Drugs arising from the kickbacks expressly and impliedly misrepresent compliance with a material condition of payment, to wit, compliance with the AKS. Claims that include items or services resulting from a violation of the AKS constitute false or fraudulent claims under the AKS. 42 U.S.C. § 1320a-7b(b).

176. By providing remuneration to physicians and other health care professionals, Astra intended to induce those physicians and other health care professionals, to recommend

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and/or prescribe Astra's Covered Drugs.

177. It was reasonably foreseeable that some of those prescriptions would be for Federal or State health care program beneficiaries and that claims for those prescriptions would be submitted to Federal health care programs. Thousands of such prescriptions or claims based on such prescriptions were, in fact, submitted to and paid for by Federal government health care programs.

X. COUNTS

COUNT ONE — FALSE CLAIMS ACT 31 U.S.C. § 3729(a)(1)(A)-(C)

178. Relators re-allege and incorporate by reference the prior paragraphs as though fully set forth herein.

179. Relators bring these claims against Defendants on behalf of the United States for treble damages and penalties under the FCA, 31 U.S.C. §§ 3729-3733, for knowingly causing to be presented false claims to Government health care programs. From on or about 2012 through the present, in this Judicial District and elsewhere throughout the United States, Defendants knowingly and willfully have violated the FCA by causing false claims to be submitted.

180. As a result of acts described above, Defendants knowingly presented, or caused to be presented, false and fraudulent claims for services that were not eligible for reimbursement for payment or approval to the United States in violation of 31 U.S.C. § 3729(a)(1)(A).

181. Further, as a result of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or false statements material to the foregoing false or fraudulent claims to get these false or fraudulent claims paid and approved by the United States, in violation of 31 U.S.C. § 3729(a)(1)(B).

182. Finally, by virtue of the acts described above, Defendants knowingly conspired

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with each other to present or cause to be presented to the United States false or fraudulent claims for payment or approval; to make, use, or cause to be made or used, a false record or statement material to a false or fraudulent claim in violation of 31 U.S.C. § 3729(a)(1)(C).

183. To the extent any of the conduct alleged herein occurred on or before May 20, 2009, Relators re-allege that Defendants knowingly violated 31 U.S.C. § 3729(a)(1), (2), and (3) prior to amendment, by engaging in the conduct complained of herein.

184. As a direct and proximate result of the Defendants' violation of the FCA, 31 U.S.C. § 3729(a)(1)(A), (B), and (C) and/or 31 U.S.C. § 3729(a)(1), (2), and/or (3), the United States has sustained damages in a substantial amount to be determined at trial and is entitled to treble damages plus a civil penalty for each violation.

185. Relators respectfully requests this Court enter judgment against the Defendants as follows: (1) awarding the United States damages in the amount of the United States' damages, trebled, as required by law; (2) imposing civil penalties as are required by law; (3) awarding attorneys' fees, costs, and expenses that Relators necessarily incurred in bringing and pressing this case forward; (4) awarding Relators the maximum amount allowed to them pursuant to the FCA; and (5) entering any such other order and further relief as this Court deems proper.

COUNT TWO — CALIFORNIA FALSE CLAIMS ACT
Cal. Gov't Code §§ 12650-12656

186. This is a claim for treble damages and civil penalties under the California False Claims Act, Cal. Gov't Code §§ 12650-12656. Relators re-allege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

187. Defendants violated the California False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of California as described herein.

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188. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of California.

189. The State of California, unaware of the false or fraudulent nature of these claims, paid such claims which the State of California would not otherwise have paid.

190. By reason of these payments, the State of California has been damaged, and continues to be damaged, in a substantial amount.

COUNT THREE — COLORADO MEDICAID FALSE CLAIMS ACT
Colo. Rev. Stat. Ann. §§ 25.5-4-303.5 to 25.5-4-310

191. This is a claim for treble damages and civil penalties under the Colorado Medicaid False Claims Act, Colo. Rev. Stat. Ann. §§ 25.5-4-303.5 to 25.5-4-310. Relators re-allege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

192. Defendants violated the Colorado Medicaid False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Colorado, as described herein.

193. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Colorado.

194. The State of Colorado, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Colorado would not otherwise have paid.

195. By reason of these payments, the State of Colorado has been damaged, and continues to be damaged, in a substantial amount.

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COUNT FOUR — CONNECTICUT FALSE CLAIMS AND OTHER PROHIBITED ACTS UNDER STATE-ADMINISTERED HEALTH OR HUMAN SERVICES PROGRAMS
Conn. Gen. Stat. Ann. §§ 4-274 to 4-289

196. This is a claim for treble damages and civil penalties under the Connecticut False Claims and Other Prohibited Acts Under State-Administered Health or Human Services Programs, Conn. Gen. Stat. Ann. §§ 4-274 to 4-289. Relators re-allege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

197. Defendants violated the Connecticut False Claims and Other Prohibited Acts Under State-Administered Health or Human Services Programs by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Connecticut, as described herein.

198. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Connecticut.

199. The State of Connecticut, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Connecticut would not otherwise have paid.

200. By reason of these payments, the State of Connecticut has been damaged, and continues to be damaged, in a substantial amount.

COUNT FIVE — DELAWARE FALSE CLAIMS AND REPORTING ACT
Del. Code Ann. tit. 6, §§ 1201-1211

201. This is a claim for treble damages and civil penalties under the Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, §§ 1201-1211. Relators re-allege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

202. Defendants violated the Delaware False Claims and Reporting Act by engaging in

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the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Delaware, as described herein.

203. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Delaware.

204. The State of Delaware, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Delaware would not otherwise have paid.

205. By reason of these payments, the State of Delaware has been damaged, and continues to be damaged, in a substantial amount.

COUNT SIX — DISTRICT OF COLUMBIA PROCUREMENT RELATED CLAIMS
D.C. Code Ann. §§ 2-381.01 to 2-381.10

206. This is a claim for treble damages and civil penalties under the District of Columbia Procurement Related Claims, D.C. Code Ann. §§ 2-381.01 to 2-381-10. Relators re-allege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

207. Defendants violated the District of Columbia Procurement Related Claims by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the District of Columbia, as described herein.

208. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the District of Columbia.

209. The District of Columbia, unaware of the false or fraudulent nature of these claims, paid such claims which the District of Columbia would not otherwise have paid.

210. By reason of these payments, the District of Columbia has been damaged, and continues to be damaged, in a substantial amount.

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COUNT SEVEN — FLORIDA FALSE CLAIMS ACT
Fla. Stat. Ann. §§ 68.081 to 68.092

211. This is a claim for treble damages and civil penalties under the Florida False Claims Act, Fla. Stat. Ann. §§ 68.081 to 68.092. Relators re-allege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

212. Defendants violated the Florida False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Florida as described herein.

213. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Florida.

214. The State of Florida, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Florida would not otherwise have paid.

215. By reason of these payments, the State of Florida has been damaged, and continues to be damaged, in a substantial amount.

COUNT EIGHT — GEORGIA FALSE MEDICAID CLAIMS
Ga. Code Ann. §§ 49-4-168 to 49-4-168.6

216. This is a claim for treble damages and civil penalties under Georgia False Medicaid Claims, Ga. Code Ann. §§ 49-4-168 to 49-4-168.6. Relators re-allege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

217. Defendants violated the Georgia False Medicaid Claims by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Georgia, as described herein.

218. As a result of the misconduct alleged herein, Defendants knowingly made, used,

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or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Georgia.

219. The State of Georgia, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Georgia would not otherwise have paid.

220. By reason of these payments, the State of Georgia has been damaged, and continues to be damaged, in a substantial amount.

COUNT NINE — HAWAI'I QUI TAM ACTIONS OR RECOVERY OF FALSE CLAIMS TO THE STATE
Haw. Rev. Stat. Ann. §§ 661-21 to 661-31

221. This is a claim for treble damages and civil penalties under the Hawai'i Qui Tam Actions or Recovery of False Claims to the State, Haw. Rev. Stat. Ann. §§ 661-21 to 661-31. Relators re-allege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

222. Defendants violated the Hawai'i Qui Tam Actions or Recovery of False Claims to the State by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Hawai'i, as described herein.

223. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Hawai'i.

224. The State of Hawai'i, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Hawai'i would not otherwise have paid.

225. By reason of these payments, the State of Hawai'i has been damaged, and continues to be damaged, in a substantial amount.

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COUNT TEN — ILLINOIS FALSE CLAIMS ACT
740 Ill. Comp. Stat. Ann. 175/1 to 175/8

226. This is a claim for treble damages and civil penalties under the Illinois False Claims Act, 740 Ill. Comp. Stat. Ann. 175/1 to 175/8. Relators re-allege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

227. Defendants violated the Illinois False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Illinois, as described herein.

228. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Illinois.

229. The State of Illinois, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Illinois would not otherwise have paid.

230. By reason of these payments, the State of Illinois has been damaged, and continues to be damaged, in a substantial amount.

COUNT ELEVEN — INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION
Ind. Code Ann. §§ 5-11-5.5-1 to 5-11-5.5-18

231. This is a claim for treble damages and civil penalties under the Indiana False Claims and Whistleblower Protection, Ind. Code Ann. §§ 5-11-5.5-1 to 5-11-5.5-18. Relators re-allege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

232. Defendants violated the Indiana False Claims and Whistleblower Protection by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Indiana, as described herein.

233. As a result of the misconduct alleged herein, Defendants knowingly made, used,

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or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Indiana.

234. The State of Indiana, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Indiana would not otherwise have paid.

235. By reason of these payments, the State of Indiana has been damaged, and continues to be damaged, in a substantial amount.

COUNT TWELVE — IOWA FALSE CLAIMS
Iowa Code Ann. §§ 685.1 to 685.10

236. This is a claim for treble damages and civil penalties under the Iowa False Claims, Iowa Code Ann. §§ 685.1 to 685.10. Relators re-allege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

237. Defendants violated the Iowa False Claims by engaging in the fraudulent and illegal practices, including knowingly presenting or causing to be presented to the Iowa Medicaid program false or fraudulent records or statements and false or fraudulent claims for payment and approval, claims which failed to disclose material violations of law, and/or concealed their actions and to avoid or decrease an obligation to pay or transmit money to the state, all in violation of the Iowa False Claims, as described herein.

238. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Iowa.

239. The State of Iowa, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Iowa would not otherwise have paid.

240. By reason of these payments, the State of Iowa has been damaged, and continues to be damaged, in a substantial amount.

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COUNT THIRTEEN — LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW
La. Stat. Ann. §§ 46:437.1 to 437.14

241. This is a claim for treble damages and civil penalties under the Louisiana Medical Assistance Programs Integrity Law, La. Stat. Ann. §§ 46:437.1 to 437.14. Relators re-allege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

242. Defendants violated the Louisiana Medical Assistance Programs Integrity Law by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Louisiana, as described herein.

243. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Louisiana.

244. The State of Louisiana, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Louisiana would not otherwise have paid.

245. By reason of these payments, the State of Louisiana has been damaged, and continues to be damaged, in a substantial amount.

COUNT FOURTEEN — MARYLAND FALSE CLAIMS ACT
Md. Code Ann., Gen. Provisions §§ 8-101 to 8-111

246. This is a claim for treble damages and civil penalties under the Maryland False Claims Act, Md. Code Ann., Gen. Provisions §§ 8-101 to 8-111. Relators re-allege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

247. Defendants violated the Maryland False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Maryland, as described herein.

248. As a result of the misconduct alleged herein, Defendants knowingly made, used,

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or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Maryland.

249. The State of Maryland, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Maryland would not otherwise have paid.

250. By reason of these payments, the State of Maryland has been damaged, and continues to be damaged, in a substantial amount.

COUNT FIFTEEN — MASSACHUSETTS FALSE CLAIMS LAW
Mass. Gen. Laws Ann. ch. 12, §§ 5A-5O

251. This is a claim for treble damages and civil penalties under the Massachusetts False Claims Law, Mass. Gen. Laws Ann. ch. 12, §§ 5A-5O. Relators re-allege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

252. Defendants violated the Massachusetts False Claims Law by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the Commonwealth of Massachusetts, as described herein.

253. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Commonwealth of Massachusetts.

254. The Commonwealth of Massachusetts, unaware of the false or fraudulent nature of these claims, paid such claims which the Commonwealth of Massachusetts would not otherwise have paid.

255. By reason of these payments, the Commonwealth of Massachusetts has been damaged, and continues to be damaged, in a substantial amount.

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COUNT SIXTEEN — MICHIGAN MEDICAID FALSE CLAIM ACT
Mich. Comp. Laws Ann. §§ 400.601 to 400.615

256. This is a claim for treble damages and civil penalties under the Michigan Medicaid False Claim Act, Mich. Comp. Laws Ann. §§ 400.601 to 400.615. Relators re-allege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

257. Defendants violated the Michigan Medicaid False Claim Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Michigan, as described herein.

258. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Michigan.

259. The State of Michigan, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Michigan would not otherwise have paid.

260. By reason of these payments, the State of Michigan has been damaged, and continues to be damaged, in a substantial amount.

COUNT SEVENTEEN — MINNESOTA FALSE CLAIMS AGAINST THE STATE
Minn. Stat. Ann. §§ 15c.01 to 15c.16

261. This is a claim for treble damages and civil penalties under the Minnesota False Claims Against the State, Minn. Stat. Ann. §§ 15c.01 to 15c.16. Relators re-allege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

262. Defendants violated the Minnesota False Claims Against the State by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Minnesota, as described herein.

263. As a result of the misconduct alleged herein, Defendants knowingly made, used,

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or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Minnesota.

264. The State of Minnesota, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Minnesota would not otherwise have paid.

265. By reason of these payments, the State of Minnesota has been damaged, and continues to be damaged, in a substantial amount.

COUNT EIGHTEEN — MONTANA FALSE CLAIMS ACT
Mont. Code Ann. §§ 17-8-401 to 17-8-416

266. This is a claim for treble damages and civil penalties under Montana False Claims Act, Mont. Code Ann. §§ 17-8-401 to 17-8-416. Relators re-allege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

267. Defendants violated the Montana False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Montana, as described herein.

268. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Montana.

269. The State of Montana, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Montana would not otherwise have paid.

270. By reason of these payments, the State of Montana has been damaged, and continues to be damaged, in a substantial amount.

COUNT NINETEEN — NEVADA SUBMISSION OF FALSE CLAIMS TO STATE OR LOCAL GOVERNMENT
Nev. Rev. Stat. Ann. §§ 357.010 to 357.250

271. This is a claim for treble damages and civil penalties under the Nevada

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Submission of False Claims to State or Local Government, Nev. Rev. Stat. Ann. §§ 357.010 to 357.250. Relators re-allege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

272. Defendants violated the Nevada Submission of False Claims to State or Local Government by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Nevada, as described herein.

273. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Nevada.

274. The State of Nevada, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Nevada would not otherwise have paid.

275. By reason of these payments, the State of Nevada has been damaged, and continues to be damaged, in a substantial amount.

COUNT TWENTY — NEW HAMPSHIRE MEDICAID FRAUD AND FALSE CLAIM N.H. Rev. Stat. Ann. §§ 167:58 to 167:62

276. This is a claim for treble damages and civil penalties under the New Hampshire Medicaid Fraud and False Claim, N.H. Rev. Stat. Ann. §§ 167:58 to 167:62. Relators re-allege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

277. Defendants violated the New Hampshire False Claims by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of New Hampshire, as described herein.

278. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of New Hampshire.

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279. The State of New Hampshire, unaware of the false or fraudulent nature of these claims, paid such claims which the State of New Hampshire would not otherwise have paid.

280. By reason of these payments, the State of New Hampshire has been damaged, and continues to be damaged, in a substantial amount.

COUNT TWENTY-ONE — NEW JERSEY FALSE CLAIMS ACT
N.J. Stat. Ann. §§ 2A:32c-1 to 2A:32c-18

281. This is a claim for treble damages and civil penalties under the New Jersey False Claims Act, N.J. Stat. Ann. §§ 2A:32c-1 to 2A:32c-18. Relators re-allege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

282. Defendants violated the New Jersey False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of New Jersey, as described herein.

283. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of New Jersey.

284. The State of New Jersey, unaware of the false or fraudulent nature of these claims, paid such claims which the State of New Jersey would not otherwise have paid.

285. By reason of these payments, the State of New Jersey has been damaged, and continues to be damaged, in a substantial amount.

COUNT TWENTY-TWO — NEW MEXICO FRAUD AGAINST TAXPAYERS ACT
N.M. Stat. Ann. §§ 44-9-1 to 44-9-14

286. This is a claim for treble damages and civil penalties under the New Mexico Fraud Against Taxpayers Act, N.M. Stat. Ann. §§ 44-9-1 to 44-9-14. Relators re-allege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

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287. Defendants violated the New Mexico Fraud Against Taxpayers Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of New Mexico, as described herein.

288. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of New Mexico.

289. The State of New Mexico, unaware of the false or fraudulent nature of these claims, paid such claims which the State of New Mexico would not otherwise have paid.

290. By reason of these payments, the State of New Mexico has been damaged, and continues to be damaged, in a substantial amount.

COUNT TWENTY-THREE — NEW YORK FALSE CLAIMS ACT
N.Y. State Fin. Law §§ 187-194

291. This is a claim for treble damages and civil penalties under the New York False Claims Act, N.Y. State Fin. Law §§ 187-194. Relators re-allege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

292. Defendants violated the New York False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of New York, as described herein.

293. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of New York.

294. The State of New York, unaware of the false or fraudulent nature of these claims, paid such claims which the State of New York would not otherwise have paid.

295. By reason of these payments, the State of New York has been damaged, and

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continues to be damaged, in a substantial amount.

COUNT TWENTY-FOUR — NORTH CAROLINA FALSE CLAIMS ACT
N.C. Gen. Stat. Ann. §§ 1-605 to 1-629

296. This is a claim for treble damages and civil penalties under the North Carolina False Claims Act, N.C. Gen. Stat. Ann. §§ 1-605 to 1-629. Relators re-allege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

297. Defendants violated the North Carolina False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of North Carolina, as described herein.

298. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of North Carolina.

299. The State of North Carolina, unaware of the false or fraudulent nature of these claims, paid such claims which the State of North Carolina would not otherwise have paid.

300. By reason of these payments, the State of North Carolina has been damaged, and continues to be damaged, in a substantial amount.

COUNT TWENTY-FIVE — OKLAHOMA MEDICAID FALSE CLAIMS ACT
Okla. Stat. Ann. tit. 63, §§ 5053-5054

301. This is a claim for treble damages and civil penalties under the Oklahoma Medicaid False Claims Act, Okla. Stat. Ann. tit. 63, §§ 5053-5054. Relators re-allege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

302. Defendants violated the Oklahoma Medicaid False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Oklahoma, as described herein.

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303. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Oklahoma.

304. The State of Oklahoma, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Oklahoma would not otherwise have paid.

305. By reason of these payments, the State of Oklahoma has been damaged, and continues to be damaged, in a substantial amount.

COUNT TWENTY-SIX — RHODE ISLAND STATE FALSE CLAIMS ACT
tit. 9 R.I. Gen. Laws Ann. §§ 9-1.1-1 to 9-1.1-9

306. This is a claim for treble damages and civil penalties under the Rhode Island State False Claims Act, tit. 9 R.I. Gen. Laws Ann. §§ 9-1.1-1 to 9-1.1-9. Relators re-allege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

307. Defendants violated the Rhode Island State False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Rhode Island, as described herein.

308. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Rhode Island.

309. The State of Rhode Island, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Rhode Island would not otherwise have paid.

310. By reason of these payments, the State of Rhode Island has been damaged, and continues to be damaged, in a substantial amount.

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COUNT TWENTY-SEVEN — TENNESSEE FALSE CLAIMS ACT
Tenn. Code Ann. §§ 4-18-101 to 4-18-108

311. This is a claim for treble damages and civil penalties under the Tennessee False Claims Act, Tenn. Code Ann. §§ 4-18-101 to 4-18-108. Relators re-allege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

312. Defendants violated the Tennessee False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Tennessee, as described herein.

313. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Tennessee.

314. The State of Tennessee, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Tennessee would not otherwise have paid.

315. By reason of these payments, the State of Tennessee has been damaged, and continues to be damaged, in a substantial amount.

COUNT TWENTY-EIGHT — TENNESSEE MEDICAID FALSE CLAIMS ACT
Tenn. Code. Ann. §§ 71-5-181 to 71-5-199c

316. This is a claim for treble damages and civil penalties under the Tennessee Medicaid False Claims Act, Tenn. Code. Ann. §§ 71-5-181 to 71-5-199c. Relators re-allege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

317. Defendants violated the Tennessee Medicaid False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Tennessee, as described herein.

318. As a result of the misconduct alleged herein, Defendants knowingly made, used,

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or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Tennessee.

319. The State of Tennessee, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Tennessee would not otherwise have paid.

320. By reason of these payments, the State of Tennessee has been damaged, and continues to be damaged, in a substantial amount.

COUNT TWENTY-NINE — TEXAS MEDICAID FRAUD PREVENTION
Tex. Hum. Res. Code Ann. §§ 36.001 to 36.132

321. This is a claim for treble damages and civil penalties under the Texas Medicaid Fraud Prevention, Tex. Hum. Res. Code Ann. §§ 36.001 to 36.132. Relators re-allege and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

322. Defendants violated the Texas Medicaid Fraud Prevention by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Texas, as described herein.

323. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Texas.

324. The State of Texas, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Texas would not otherwise have paid.

325. By reason of these payments, the State of Texas has been damaged, and continues to be damaged, in a substantial amount.

COUNT THIRTY — VERMONT FALSE CLAIMS ACT
Vt. Stat. Ann. tit. 32, §§ 630-642

326. This is a claim for treble damages and civil penalties under the Vermont False

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Claims Act, Vt. Stat. Ann. tit. 32, §§ 630-642. Relators re-allege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

327. Defendants violated the Vermont False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Vermont, as described herein.

328. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Vermont.

329. The State of Vermont, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Vermont would not otherwise have paid.

330. By reason of these payments, the State of Vermont has been damaged, and continues to be damaged, in a substantial amount.

COUNT THIRTY-ONE — VIRGINIA FRAUD AGAINST TAXPAYERS ACT
Va. Code Ann. §§ 8.01-216.1 to 8.01-216.19

331. This is a claim for treble damages and civil penalties under the Virginia Fraud Against Taxpayers Act, Va. Code Ann. §§ 8.01-216.1 to 8.01-216.19. Relators re-allege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

332. Defendants violated the Virginia Fraud Against Taxpayers Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the Commonwealth of Virginia, as described herein.

333. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Commonwealth of Virginia.

334. The Commonwealth of Virginia, unaware of the false or fraudulent nature of

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these claims, paid such claims which the Commonwealth of Virginia would not otherwise have paid.

335. By reason of these payments, the Commonwealth of Virginia has been damaged, and continues to be damaged, in a substantial amount.

COUNT THIRTY-TWO — WASHINGTON MEDICAID FRAUD FALSE CLAIMS ACT WASH. REV. CODE ANN. §§ 74.66.005 TO 74.66.130

336. This is a claim for treble damages and civil penalties under the Washington Medicaid Fraud False Claims Act, Wash. Rev. Code Ann. §§ 74.66.005 to 74.66.130. Relators re-allege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

337. Defendants violated the Washington Medicaid Fraud False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Washington, as described herein.

338. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Washington.

339. The State of Washington, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Washington would not otherwise have paid.

340. By reason of these payments, the State of Washington has been damaged, and continues to be damaged, in a substantial amount.

XI. PRAYER FOR RELIEF

WHEREFORE, Relators respectfully request this Court enter judgment against the Defendants as follows: (1) awarding the United States damages in the amount of the United States' damages, trebled, as required by law; (2) imposing civil penalties as are required by law; (3) awarding attorneys' fees, costs, and expenses that Relators necessarily incurred in bringing

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and pressing this case forward; (4) awarding Relators the maximum amount allowed to them pursuant to the FCA; and (5) entering any such other order and further relief as this Court deems proper.

XII. DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rule of Civil Procedure, Relators hereby demand a trial by jury.

DATED this 1st day of September, 2017.

KELLER ROHRBACK L.L.P.

By _____

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